REMARKS

The Restriction Requirement

The Examiner has required a new restriction of the claims of this application under 35 U.S.C. § 121. This restriction supercedes the previous restriction requirement of June 8, 2004. Applicants affirm the election, made during a December 16, 2004 telephone conversation between applicants' attorney and the Examiner, of the invention of Group I (claims 19-20 and 36-38). These claims are drawn to compositions. Applicants also affirm the election of compound no. 100, as the species for substantive examination on the merits.

Applicants made these elections with traverse. They also made them expressly without waiver of their rights to file for and to obtain claims directed to the non-elected subject matter in this application or in divisional or continuing applications claiming priority and benefit from this application under 35 U.S.C. § 120.

The Examiner has withdrawn claims 21-35 (method of treatment claims) and 37-38 (not readable on the elected species - compound 100) from further consideration. Applicants will request rejoinder of these claims with the elected composition and elected species claims, if and when any one of those is found allowable. (MPEP §821.04.)

Applicants had previously canceled claims 1-18. Applicants have now withdrawn claims 21-35 and 37-40. Claims 19, 20 and 36, therefore, remain pending in the application. The inventorship is still correct.

Rejections

35. U.S.C. §102(b) – US Patent 3,573,051

The Examiner has rejected claims 19-20 and 36 under 35 U.S.C. §102(b) as being anticipated by US Patent 3,573,051 ("the '051 patent"). Specifically, the Examiner states that compound III, in column 2 of the '051 patent, anticipates the claimed composition, in as much as the compound is an amide and thus soluble in water, a well known pharmaceutical composition carrier, absent evidence to the contrary. Applicants traverse.

The pending claims recite a pharmaceutical composition that requires a compound of claim 19 and a pharmaceutically acceptable carrier, adjuvant, or vehicle. The application defines a "pharmaceutically acceptable carrier or adjuvant [as] a carrier or adjuvant that may be administered to a patient, together with a compound of this invention, and which does not destroy the pharmacological activity thereof and is nontoxic when administered in doses sufficient to deliver a therapeutic amount of the compound" (page 45, lines 24-34). The Technical Field of the Invention teaches that the claimed pharmaceutical compositions may be advantageously used as therapeutic agents for inosine-5'-monophosphate dehydrogenase (IMPDH) mediated processes (page 1, lines 9-12). More specifically, the application discloses that the claimed pharmaceutically acceptable compounds are useful as IMPDH inhibitors and can be used for the treatment or prophylaxis of transplant rejection and autoimmune disease (page 6, lines 5-11). Finally, the application teaches that the claimed pharmaceutical compositions are useful as multi-component compositions with other therapeutic and prophylactic agents for antiviral, anti-tumor, anti-

cancer, anti-inflammatory, antifungal, antipsoriatic immunosuppressive chemotherapy and restenosis therapy regiments (page 6, lines 12-17).

The '051 patent teaches none of those things. It provides absolutely no disclosure that Compound III is useful as a part of a pharmaceutical composition. Nor does the '051 patent teach using Compound III with a pharmaceutically acceptable carrier. Rather, the '051 patent discloses a dye-forming system that is useful in producing photographic copies. See, e.g., column 2, lines 14-17. In that use, Compound III is a part of an at least two-component dye-forming mixture, including at least one diazonium salt and possibly a yellow coupler. See, col. 2, line 25 - col. 3, line 50; claims 1 and 2. And, in that mixture no pharmaceutically acceptable carrier, adjuvant or vehicle is used or suggested. Indeed, the dye forming mixture is employed as a film after it is dispersed in a polymer matrix and coated on a solid support. See, e.g., col. 4, lines 34-37. As shown in Example 1, the polymer matrix is coated on the solid support in an ethylene chloride-ethanol solution. Thus, nothing within the four corners of the '051 patent discloses using Compound III in therapy or as part of a pharmaceutical composition. The '051 patent therefore does not anticipate the pending claims.

Disregarding this total lack of disclosure in the '051 patent, the Examiner asserts that the '051 patent anticipates the claimed compositions inasmuch as Compound III is an amide and is soluble in water, which the Examiner argues is a pharmaceutical composition carrier. The Examiner's hypothesis goes far beyond the disclosure of the '051 patent. For anticipation, a patent must disclose "each and every element of the claim". The '051 patent does not. Accordingly, the '051 patent cannot and does not anticipate the

pending claims. Applicants request that the Examiner withdraw this rejection and allow claims 19-20 and 36.

35 U.S.C. §101 – Double Patenting – US Patent 6,653,309

The Examiner has rejected claim 19 under 35 U.S.C. §101 as claiming the "same" invention as claim 19 of US Patent 6,653,309 ("the '309 patent"). Applicants traverse.

Claim 19 of the '309 patent does not claim the "same" invention as claim 19 of this application. For example, the proviso in claim 19 of the '309 patent (col. 78, lines 49-55) is not present in claim 19 of the pending application. Therefore, pharmaceutical compositions could literally fall within claim 19 of this application yet not literally fall within claim 19 of the '309 application. Hence, there is no "same" invention double patenting. To the extent that the Examiner believes there is obvious-type double patenting, applicants are willing to file one or more terminal disclaimers upon allowance of claim 19 in this application.

Obviousness-Type Double Patenting – U.S. Patent 6,653,309

The Examiner has rejected claims 20 and 36 for obviousness-type double patenting over claim 19 of the '309 patent. The Examiner acknowledges that the conflicting claims of the instant application are not identical to claim 19 of the '309 patent. However, the Examiner alleges that claims 20 and 36 are not patentably distinct from claim 19 of the

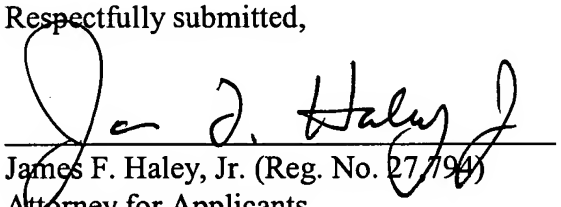
'309 patent because the definition of X in the instant claim overlaps with the corresponding definition in the '309 patent.

Applicants will file one or more terminal disclaimers, in compliance with 37 C.F.R. §1.321(c), to obviate the obviousness-type double patenting rejection upon allowance of any of the conflicting claims in this application.

CONCLUSION

Applicants request that the Examiner consider the above remarks, withdraw all the outstanding rejections, and allow the pending claims 19-20 and 36 to pass to issue.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)
Attorney for Applicants
c/o Fish & Neave IP Group
ROPES & GRAY LLP
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1105
Tel.: (212) 596-9000
Fax : (212) 596-9090